Remarks:

Claims 1, 2, 5–7, 9–11, 13, 14, and 17–21 are currently pending with claims 1, 18, and 20 being independent. No claims are presently amended or cancelled. This Response follows an Examiner's Answer dated October 5, 2007. Declarations under 37 C.F.R. § 1.132 signed by Rhetah Kwan and Debi Whitson have been submitted with this Response as evidence supporting the arguments set forth below.

The Declarations

Rhetah Kwan is an uninterested party with twelve years of experience in the electronic medical record industry implementing electronic medical record software systems and providing training and support services to companies using the systems. Her career in the electronic medical record industry culminated in 2002, the year after the present Application was filed.

The declaration signed by Rhetah Kwan illustrates, among other things, a long-felt need in the industry for an improved method of receiving information from a patient and adding the information to the patient's electronic medical record. As indicated in paragraphs 8 and 9 of Ms. Kwan's declaration, she was aware of a need in the industry to provide a more efficient manner of adding information provided by a patient to the patient's electronic medical record as early as 1990, which need persisted at least until she left the industry in 2002.

Rhetah Kwan's declaration further illustrates that the invention as recited in claim 1 of the Application would not have been obvious to a person skilled in this art at the time the invention was made. For example, as indicate in paragraph 5 of Ms. Kwan's declaration, Ms. Kwan was not aware that the functionality recited in claim 1 could be performed.

The declaration signed by Debi Whitson illustrates, among other things, that the invention as recited in claim 1 was not obvious to skilled artisan's at the time of the

invention, and further that the invention as recited in claim 1 has been commercially successful. As indicated in paragraph 5 of Debi Whitson's declaration, she has sold more than 900 systems embodying the invention recited in claim 1. As indicated in paragraph 8, those skilled in the art, as well as Ms. Whitson herself, were not aware that the steps recited in claim 1 could be successfully performed until she developed the invention.

Regarding the rejection of claims 1, 4, 6, 18 and 20, the Examiner has failed to identify a reason why a person of ordinary skill in the art would combine Kimak and Kraftson as proposed by the Examiner.

In the Office Action dated February 28, 2007 ("OA"), claims 1, 4, 6, and 18–21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kimak in view of Kraftson. The Examiner asserted that at "the time of Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to use paper machine-readable questionnaires to obtain patient information." (OA, page 7). Appellant strongly disagrees.

The Examiner has failed to identify a reason why a person of ordinary skill in the art would combine Kimak with Kraftson as proposed by the Examiner. First, the system of Kraftson manages anonymous data records, while the system of Kimak manages patient-specific electronic medical records that are governed by laws restricting their use. As explained above in the sections titled "The Application Invention" and "Summary of U.S. Patent No. 6,151,581 to Kraftson," the data records managed by Kraftson are entirely different than the electronic medical records managed by Kimak. Electronic medical records, for example, are subject to laws and regulations such as HIPAA that govern their use and distribution. Kimak alludes to the restraints such laws and regulations place on the system, disclosing, for example, that point of service care providers must "enter the system through an approved method," and that providers can view data entered by other providers "provided proper disclosure forms have been obtained." (¶¶ 64, 76, *emphasis added*).

This is a significant distinction because the laws regulating the maintenance and use of electronic medical records are an obstacle to importing scan-card data into a patient-specific electronic medical record. Kimak discloses using the HL7 standard to communicate electronic medical record data between computer systems, and Kraftson discloses storing anonymous scan card data in anonymous data records, but the prior art does not contemplate using HL7 or any other means to communicate data from a card scanning machine to a patient-specific electronic medical record. As explained in the Amendment dated June 20, 2006 (and supported by evidence submitted in an information disclosure statement accompanying the Amendment), for example, HL7 laboratory records are used for traditional laboratory tests, such as chemistry, hematology, and radiology, and—aside from Applicant's invention—are not used to import data from a scan-card machine into a patient's electronic medical record. Kraftson teaches that the records are anonymous so that "there is no danger of a patient's confidential information being inadvertently released," thus teaching away from the use of patient-specific data records. (Col. 12, lines 55–57). Kimak, in contrast, must use patient-specific electronic medical records, otherwise the records would be of no use to a physician viewing them. Because the system of Kimak is incompatible with the system of Kraftson, a person skilled in this art would have not reason to combine Kimak and Kraftson as proposed by the Examiner.

Second, even if the privacy laws and regulations associated with patient-specific electronic medical records could somehow be overcome to combine Kimak with Kraftson, the system of Kraftson never associates information collected from patients or physicians with particular patients or physicians, but rather collects and maintains the information anonymously. Therefore, it would have no use with Kimak because Kimak must be able to associate patient information with particular patients to be of any use. (*See, e.g.*, Kimak, ¶ 94, FIG. 8). Furthermore, the system of Kraftson teaches away from identifying patient or physician information with particular patients or physicians because Kraftson uses the information for statistical purposes. (Kraftson, col. 5, lines 23–38).

Third, the system of Kimak does not import information into a patient's electronic medical record, as recited in claim 1, but rather uses electronic medical records already

created by physicians. The system disclosed in Kimak gleans information from the medical records to present to users, and even stores entire copies of medical records on physicians' computer systems, but does not import information into electronic medical records. Therefore, Kimak and Kraftson considered in combination fail to teach any form of importing information received from a patient to a patient-specific electronic medical record, much less "arranging the data stream [from a scanning type machine] into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's patient-specific electronic medical record . . ."

Fourth, the system of Kimak does not receive information directly from users, only from remote servers (¶ 66). Kimak is interested only in the treatment history—in this case immunizations—which is information obtained from physicians, not from patients. Because the system disclosed in Kimak is intended and designed for use only with treatment history data obtained from remote computer systems, there is no suggestion or motivation to modify Kimak as proposed in the Office Action to receive data directly from a patient via a machine-readable questionnaire.

Finally, neither Kraftson nor Kimak discloses how the information from the patient survey forms of Kraftson could be arranged "into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's" electronic medical record, as recited in claim 1.

In support of her assertion that "it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teachings of Kraftson to use paper machine-readable questionnaires to obtain patient information," the Examiner states that "[o]ne would have been motivated to include this feature to provide a user friendly, easily accessible manner for physicians to monitor patients and their practices, without disrupting the physician's practice." (OA, page 7). This is exactly the type of "conclusory statement" the Supreme Court recently rejected as a grounds for forming a sustainable obviousness rejection, and the Examiner's assertion clearly falls short of the required "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in KSR*, 2007 WL

1237837 at *13. The Examiner fails, for example, to identify why a person skilled in this art would believe that the proposed combination would result in the alleged benefits.

For at least these reasons, a person of ordinary skill in this art would have no reason to combine Kimak and Kraftson as proposed by the Examiner.

Regarding the rejection of claim 1 under 35 U.S.C. § 103(a) over Kimak in view of Kraftson, Kimak and Kraftson do not teach or suggest each limitation of claim 1.

Regarding the rejection of claim 1, the Examiner has failed to establish the requisite *prima facie* case of obviousness because the Examiner has failed to identify a reference or combination of references that teach or suggest each limitation of claim 1. Even if Kimak is indiscriminately combined with Kraftson, for example, the combination does not teach or suggest "sending the formatted data to an assigned location for importing into the patient's patient-specific electronic medical record, wherein the patient's electronic medical record contains patient-specific, clinical information regarding the patient's health," as recited in claim 1.

The system of Kimak includes "an electronic medical record *registry* system" (¶ 33, emphasis added), wherein the system accesses electronic medical records from "a plurality of medical service provider databases" and presents information from those records to "registered point of service care providers" as a complete medical history of the patient. (Kimak, ¶¶ 47, 74, 75; FIG. 3). While Kimak discloses "merging" medical records (¶ 12), this merging operation involves merging information from multiple medical records into a single "view" or user interface element, and does not involve creating a new medical record. Kimak expressly discloses, for example, that "the merging does not result in creation of a storage location for a new record." (¶ 35). Moreover, when electronic medical records are communicated to the main registry database, the medical records are sent in their entirety and replaced by new, updated records when necessary. (¶¶ 77–81). Thus, information is never imported into a medical record, as recited in claim 1.

For at least this reason, Kimak does not teach or suggest "sending the formatted

data to an assigned location for importing into the patient's patient-specific electronic medical record, wherein the patient's electronic medical record contains patient-specific, clinical information regarding the patient's health," as recited in claim 1.

Kraftson also fails to teach or suggest "sending the formatted data to an assigned location for importing into the patient's patient-specific electronic medical record, wherein the patient's electronic medical record contains patient-specific, clinical information regarding the patient's health." The invention disclosed in Kraftson does not deal with electronic medical records that contain patient-specific, clinical information regarding the patient's health because, for example, the information gathered via the survey is stored in an anonymous database and used exclusively for statistical analyses based on patient satisfaction.

Column 6, lines 10–18 of Kraftson read:

> The System further includes a Data Analysis Processor 108 for analyzing the Physician/Patient/Management information according to selected data analysis packages such as Statistical Package for the Social Sciences (SPSS) or SAS, a Report Generation Module 110 for generating formatted reports containing results determined by the Data Analysis Processor 108, and an Outcomes Measurement Module 112 for recording and tracking performance of the System.

As can be seen, this section discloses analyzing information and generating a "formatted report," but fails to even suggest importing data "into the patient's patient-specific electronic medical record," as recited in claim 1. As explained above, a patient's electronic medical record is not a report containing results of an automated data analysis, but rather a private record containing that patient's personal, patient-specific, medical information that is viewable by a physician at the time the patient receives care from the physician.

Furthermore, Kraftson expressly teaches that the system disclosed therein generates two kinds of reports: 1) "a periodic report which summarizes general information about a quality level of the practice," and 2) "real time reports in response to physician queries" such as where a physician needs "information comparing the historical data concerning satisfaction of patient treatment in order for the physician to determine where a recently implemented change in treatment regimen improves or decreases patient

satisfaction." (Kraftson, col. 8, lines 39–63, *emphasis added*). These reports are clearly not patient-specific electronic medical records viewable at the time of care, which is further evidenced by Kraftson's disclosure that physicians must "dial up" a report generation module, and receive "periodic practice reports" or "printed reports." (*Id.*, col. 5, lines 12–16).

It would not have been obvious to one of ordinary skill in the art to modify Kraftson to send "formatted data to an assigned location for importing into the patient's patient-specific electronic medical record, wherein the patient's electronic medical record contains patient-specific, clinical information regarding the patient's health," as recited in claim 1. For example, adding information to a patient's medical record must be done in a manner that conforms with the privacy requirements described above, which, prior to Applicant's invention, was done manually with software accessible only by physicians and trained medical staff. Furthermore, Kraftson expressly teaches that the information collected from patients is anonymous satisfaction information, and that automated analyses of the information are shared among physician groups. These teachings are incompatible with the use of electronic medical records containing patient-specific, clinical information regarding the patient's health, which are subject to HIPAA and other privacy laws and regulations.

For at least the reasons set forth above, neither Kimak nor Kraftson teaches or suggests "sending the formatted data to an assigned location for importing into the patient's patient-specific electronic medical record, wherein the patient's electronic medical record contains patient-specific, clinical information regarding the patient's health," as recited in claim 1. Furthermore, Kimak and Kraftson considered in combination also fail to teach or suggest this element of claim 1. Kimak teaches sharing existing medical records between systems to create a medical history of one or more patients, but does not teach or suggest importing data into a patient's electronic medical record. Kraftson teaches away from using electronic medical records altogether by teaching using other forms of records that non-patient specific information and that are anonymous.

Regarding the rejection of claim 4 under 35 U.S.C. § 103(a) over Kimak in view of Kraftson, Kimak and Kraftson do not teach or suggest each limitation of claim 4.

Claim 4 depends from claim 1, and recites "wherein the machine readable questionnaire includes questions concerning the systems making up the human body with designated locations for patient responses." All of the arguments set forth above in relation to the rejection of claim 1 also apply to the rejection of claim 4. Additionally, neither Kimak nor Kraftson, considered alone or in combination, teach or suggest the additional limitations recited in claim 4.

Kimak does not involve a machine-readable questionnaire, and the survey-forms disclosed in Kraftson do not include questions concerning "the systems making up the human body," but rather satisfaction with the physician's services. Because the survey-forms are anonymous and relate to patient satisfaction, a person skilled in the art would have no reason to modify Kimak to use machine readable questionnaires including "questions concerning the systems making up the human body with designated locations for patient responses."

Regarding the rejection of claim 6 under 35 U.S.C. § 103(a) over Kimak in view of Kraftson, Kimak and Kraftson do not teach or suggest each limitation of claims 6.

Claim 6 depends from claim 1, and recites "further comprising the step of converting and arranging the data stream to a defined set of data structures simulating the protocol of Health Level Seven (HL7)." All of the arguments set forth above in relation to the rejection of claim 1 also apply to the rejection of claim 6. Additionally, neither Kimak nor Kraftson, considered alone or in combination, teach or suggest the additional limitations recited in claim 4 because the prior art teaches using HL7 laboratory records exclusively for traditional laboratory tests, such as blood tests, and does not contemplate using HL7 laboratory records to communicate information relating to the patient's "medical history, environment, and symptoms." Furthermore, a skilled artisan will recognize that HL7 cannot be used with the system taught by Kraftson because HL7 requires the use of patient-

specific identifiers, which cannot be present in the anonymous records disclosed by Kraftson.

Applicant submitted various references in an Information Disclosure Statement on April 3, 2006, that indicate HL7 laboratory records have been used exclusively for traditional laboratory tests. According to these articles, the healthcare industry is standardizing the format in which data is communicated from laboratories to health care providers, such as hospitals and doctors' offices, and to that end has created the Logical Observation Identifier Names and Codes (LOINC) database. The LOINC database is a list of tests and matching codes used to identify each test. The following discussion shows that the laboratory tests included in the LOINC database are strictly traditional laboratory tests, such as blood tests, urine tests, and so forth, illustrating that the prior art did not contemplate—and indeed still does not contemplate—including medical history, symptom, and environment information in HL7 laboratory records.

The article entitled "LOINC, a Universal Standard for Identifying Laboratory Observations: A 5-Year Update" by McDonald et al. ("McDonald"), explains that the

> "Logical Observation Identifier Names and Codes (LOINC) database provides a universal code system for reporting laboratory and other clinical observations. Its purpose is to identify observations in electronic messages such as Health Level Seven (HL7) observation messages, so that when hospitals, health maintenance organizations, pharmaceutical manufacturers, researchers, and public health departments receive such messages from multiple sources, they can automatically file the results in the right slots of their medical records, research, and/or public health systems."

(McDonald, page 2, emphasis added).

Thus, the LOINC is a universal standard for formatting laboratory records. McDonald further explains that

> "[a]s of July 2002, the LOINC database carried records for more than 30,000 different observations. Each record carries the formal six-part LOINC name; the LOINC code, a number with a check digit (see Table 1); the observation class (e.g., chemistry, hematology, and radiology); related names (to assist searches of the database); and other attributes."

(McDonald, page 5, emphasis added).

Therefore, the LOINC database is a standard for communicating laboratory records,

such as HL7 laboratory records, to hospitals from laboratories and relates only to traditional laboratory test measurements, such as "chemistry, hematology, and radiology."

The article entitled "Logical observation identifier names and codes (LOINC) database: a public use set of codes and names for electronic reporting of clinical laboratory test results" by Forrey et al. ("Forrey"), also discusses the character and purpose of the LOINC database. Forrey explains that the LOINC database provides a universal set of test identifiers that all laboratories may use to electronically communicate test results from laboratories to the laboratories' clients via standards such as HL7. (Forrey, page 81).

Forrey explains that "each LOINC observation name identifies a distinct laboratory observation" and includes up to six parts, where the six parts are listed in table 1. (Forrey, page 83). One of the parts listed in table 1 is the "[k]ind of property measured or observed." On page 84, Forrey explains that "[a] selected list of the most common LOINC kinds of properties is shown in Table 3." Table 3 lists the following properties: substance concentration; catalytic concentration; catalytic content; mass concentration; mass content; mass concentration ratio; mass rate, for excretions; and volume rate, for clearances. These properties clearly related only to traditional laboratory tests. This is but one example.

In summary, Forrey and McDonald show that the LOINC database of laboratory test codes is limited to traditional laboratory tests, such as chemical, hematological, and radiological tests. Because the LOINC database is intended to include a comprehensive or nearly comprehensive list of tests communicated between laboratories and healthcare providers, the prior art clearly does not contemplate formatting information relating to medical history, environment, and symptoms into an HL7 laboratory record and communicating the record to an electronic medical record interface engine, as recited in claim 6.

Furthermore, these various references relating to the LOINC database demonstrate that the prior art did not contemplate formatting data received from a patient's questionnaire so that the data is in the form of an HL7 laboratory record. Rather, the references show that only data derived in a laboratory will be so formatted.

Regarding the rejection of claim 18 under 35 U.S.C. § 103(a) over Kimak in view of Kraftson, Kimak and Kraftson do not teach or suggest each limitation of claim 18.

Claim 18 recites some limitations that are similar to those of claim 1, therefore the arguments set forth above in relation to the rejection of claim 1 also apply to the rejection of claim 18. Claim 18 further recites "presenting the information to a physician as part of the patient's personal electronic medical record."

Kimak does not disclose the use of forms to collect patient information, as explained above, much less "communicating the [scanned and] formatted data to an electronic medical record interface and adding the information to the patient's personal medical record" and "presenting the information to a physician as part of the patient's electronic medical record," as recited in claim 18.

Kraftson also fails to teach or suggest these limitations. Kraftson, for example, discloses use of anonymous survey forms to gather information about satisfaction with a physician's services. (*See supra*, page 8). An anonymous survey form cannot be associated with a "patient's personal medical record [containing] patient-specific, clinical information," and information about a patient's satisfaction with a physician's services cannot be presented to the physician before the physician renders the services.

Finally, the combination of Kimak and Kraftson does not teach or suggest these limitations. Kimak discloses a registry system for gathering information from existing electronic medical records stored on various computer systems, while Kraftson discloses a system for collecting anonymous patient survey information relating to patient satisfaction. Thus, the teachings of Kimak and Kraftson considered in combination fail to teach or suggest "presenting the information to a physician as part of the patient's electronic medical record," as recited in claim 18.

For at least these reasons, neither Kimak nor Kraftson, considered singly or in combination, teaches or suggests each element of claim 18, including "presenting the information to a physician as part of the patient's personal electronic medical record."

Regarding the rejection of claim 20 under 35 U.S.C. § 103(a) over Kimak in view of Kraftson, Kimak and Kraftson do not teach or suggest each limitation of claim 20.

Claim 20 recites some limitations that are similar to those of claims 1, 6, and 18, therefore the arguments set forth above in relation to the rejection of claims 1, 6, and 18 also apply to the rejection of claim 20.

Claim 20 recites "receiving from the patient, prior to a visit with the physician, a machine-readable printed form filled out by the patient and containing information about a health status of the patient including the patient's medical history, environment, and symptoms." Neither Kimak nor Kraftson, considered singly or in combination, teaches or suggests this limitation. As explained above, Kimak does not disclose the use of machine-readable printed forms at all. Kraftson discloses the use of "machine-readable surveys," but discloses use of anonymous survey forms to gather information about satisfaction with a physician's services (*See supra*, page 8), not a "health status of the patient including the patient's medical history, environment, and symptoms" as recited in claim 20. Furthermore, the surveys disclosed in Kraftson cannot be received prior to a visit with a physician because information about satisfaction with a physician's services cannot be provided prior to the rendering of those services.

Claim 20 further recites "electronically scanning the printed form to convert the information to machine-processable data and to communicate the data to a computer." It should be noted that the printed form scanned in this step is the form filled out by the patient with a "health status of the patient including the patient's medical history, environment, and symptoms" and received from the patient prior to a visit with the physician. Neither Kimak nor Kraftson discloses receiving such a form from a patient, much less electronically scanning the form as recited in this step of claim 20. As explained above, Kraftson discloses using anonymous survey forms with patient satisfaction information, and a person skilled in this art would have no reason to modify Kraftson to include the type of form recited in claim 20 because of the obstacles, such as HIPPA, explained above.

Claim 20 further recites "formatting the machine-processable data with the computer so that the data is in the form of a Health Level Seven laboratory record, wherein the laboratory record includes the information form the printed form and information identifying an electronic medical record that is personal to the patient." It should be noted that the machine-processable data that is formatted in this step includes the "health status of the patient including the patient's medical history, environment, and symptoms" received from the patient on the printed form. Prior to appellant's invention, formatting data received from a patient in this manner so that the data is in the form of a Health Level Seven laboratory record was never contemplated in the art because, for example, the Health Level Seven standard was not developed, nor has it been used (other than Appellant's invention) for this purpose. The discussion set forth above and the references cited herein clearly established that the claim invention represents a novel use of the HL7 standard that has never even been contemplated by others skilled in this art.

Claim 20 further recites "presenting the information to a physician as part of the patient's personal electronic medical record." Neither Kimak nor Kraftson, considered singly or in combination, teaches or suggests each element of claim 20, including "presenting the information to a physician as part of the patient's personal electronic medical record."

For at least these reasons, as well as for reasons set forth above in relation to the rejections 1, 6, and 18, Kimak and Kraftson, considered singly or in combination, fail to teach or suggest each element of claim 20.

Conclusion

For at least the reasons set forth above, the Examiner has failed to identify a reason why a person of ordinary skill in the art would combine Kimak and Kraftson. The Examiner has further failed to identify a reference or combination of references that teach or suggest each limitation of claim 1, claim 4, claim 6, claim 18, and claim 20. Therefore, Applicant respectfully submits that claims 1, 2, 4–6, 9–11, 13–14, and 17–21 are now in allowable

condition and requests a Notice of Allowance.

In the event of further questions, the Examiner is urged to call the undersigned. Any additional fee which is due in connection with this amendment should be applied against our Deposit Account No. 19-0522.

Respectfully submitted,

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